DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-15-15TG]

Agency Forms Undergoing Paperwork Reduction Act Review

The Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity

of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Promotion of the National ALS Registry to Non-referral Centers — New — Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

ATSDR is requesting a two-year OMB approval for the information collection project entitled "Promotion of the

National ALS Registry to Non-referral Centers". ATSDR is authorized by the Public Health Law No: 110-373, ALS Registry Act to (1) develop a system to collect data on amyotrophic lateral sclerosis (ALS) and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, or progress to ALS; and (2) establish a national registry for the collection and storage of such data to develop a population-based registry of cases.

ATSDR implemented the National ALS Registry (Registry) in 2009 using an algorithm applied to national administrative databases. A self-registration component was launched in October 2010.

The primary goal of the Registry is to obtain more complete information on the likely prevalence of ALS and to better describe the demographic characteristics (age, race, sex, and geographic location) of those with ALS. The secondary goal of the registry is to collect additional information on potential risk factors for ALS including, but not limited to, family history of ALS, smoking history, and military service.

The Registry's case ascertainment methodology required validation; therefore, ATSDR established State and Metropolitan ALS Surveillance Projects (Surveillance Projects). In order to avoid biasing results from the Surveillance Projects' evaluation

of the Registry's completeness, staff were instructed to not promote the Registry during the surveillance period.

The proposed project is a new component to be added to the existing Registry and ALS Surveillance Projects to increase self-enrollment rates of those with ALS. According to the Morbidity and Mortality Weekly Report (MMWR) published in 2014, the proportion of cases identified via self-registration was lower than those identified in the administrative data for the period October 2010-December 2011. On-going self-registration is critical because not all persons with ALS can be identified through the algorithm, and only self-registering persons with ALS can complete the risk-factor surveys. Therefore, efforts to increase Registry awareness among non-referral center neurology practices/neurologists is needed to increase self-enrollment of persons with ALS.

This new information collection aims to evaluate educational and promotional outreach activities among select non-referral/non-specialty center neurology practices and is a result of the need to promote the Registry among neurologists who do not work at major ALS referral centers. The following objectives are set for this project:

1) To implement a pilot project to conduct educational and promotional outreach activities at non-referral center

neurology practices in the US, to inform neurologists and their staff about the Registry;

2) To encourage neurologists to inform their patients about the Registry, and to increase persons with ALS self-enrollment in the Registry through the web portal via the use of existing Registry brochures, pamphlets, and factsheets; and

3) To examine the effectiveness of educational and promotional outreach activities by reviewing persons with ALS self-enrollment rates before, during, and after the project period.

By increasing self-enrollment rates, ATSDR will be able to produce more accurate estimates of prevalence of ALS, and collect risk-factor survey data from a more representative sample of persons with ALS nationwide which will allow ATSDR to fulfill its congressional mandate under the ALS Registry Act.

To achieve these objectives, a four group educational and promotional outreach project respondents has been designed.

Data for the study will be gathered by means of initial eligibility phone calls and follow-up phone calls and mailings, for neurologists who do or would diagnose/care for patients with ALS. Train-the trainer sessions will be conducted to educate neurologists about the Registry and key informant interviews with neurologists will be done to better understand their

knowledge, attitudes, and beliefs about the Registry, and to gather additional information about the currently deployed Registry materials.

Participation is voluntary. The total annual burden hours for the proposed project is 344. There is no cost to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Neurologist Support Staff	Initial Phone Call	1,900	1	6/60
Neurologist Support Staff	Fax to Determine Provider Status	380	1	1/60
Neurologist Support Staff	Follow-up Phone Call 1 (One-Week Post Mailing)	950	1	3/60
Neurologist Support Staff	Follow-up Phone Call 2 (Three Months Post Mailing)	950	1	3/60
Neurologist Support Staff	Fax to Determine if Mailing was Received	190	1	1/60
Neurologist /Neurologist Support Staff	Train-the-trainer Invitation Phone Call	60	1	6/60
Neurologist /Neurologist Support Staff	Key Informant Interview Invitation Phone Call	64	1	6/60

Neurologist /Neurologist Support Staff	Train-the-trainer	21	1	1
Neurologist	Key Informant Interview	16	1	1

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